

Outpatient Documentation Requirements for MAT

A. The Physician's Initial Assessment should include the following:

1. Date of patient contact (month/day/year)
2. Identifying information
3. Location where service was provided
4. Reason for visit

5. Substance Use history
 - a. If seeking medication assisted treatment for opioid use disorder with methadone or buprenorphine, the following need to be documented:
 - i. Physical withdrawal (signs & symptoms) from an opioid or that patient meets exception criteria.
 - ii. The DSM 5 criteria for opioid use disorder that patient meets.
 - iii. Duration of opioid use – for methadone maintenance treatment, must be verifiable from source other than patient's report or the report of family or friends, such as:
 1. Prior treatment episode(s) for opioid use disorder (with or without use of medication to treat withdrawal).
 2. Medical records indicating prior observation or diagnosis of opioid use disorder.
 3. Legal records showing multiple incarcerations related to opioid use or presence of opioid withdrawal while incarcerated.
 4. Physical exam findings consistent with opioid use of greater than one-year duration.
 - iv. The date, time, amount, and type of last opioid used.
 - v. Results of onsite urine drug test.
 - vi. Result of onsite urine pregnancy test (when applicable).
 - b. List of substances used, other than prescribed or as directed (OTC), including licit and illicit substances (sedatives, stimulants hallucinogens, alcohol, tobacco, etc)
 - i. Age at first use.
 - ii. Amount used, past and current.
 - iii. Duration of use, longest period of abstinence.
 - iv. If applicable, history of medical complications of use such as physical withdrawal, blackout, hospitalizations, heart attack, stroke, seizure, hepatic impairment, major accidents, or injuries associated with substance use.
 - v. If applicable, adverse events associated with use such as incarceration, homelessness, inability to work or attend school, loss of relationships/custody of children.

- c. Prior treatment episodes:
 - i. Type of treatment(s) (inpatient or outpatient).
 - ii. Whether medication was used (for detox or maintenance) and efficacy.
 - iii. Approximate number of prior treatment episodes.
 - iv. Whether treatment was completed.
 - v. Duration of abstinence after treatment.
6. Medical History (note any concerns about fitness for MAT)
 - a. Past/current infections including endocarditis, hepatitis, tuberculosis, syphilis, soft tissue.
 - b. Pregnancy status and outcomes of past pregnancies.
 - c. Chronic diseases including respiratory, cardiac, GI, GU, metabolic, neurological.
 - d. Mental health diagnosis, note history of suicidality, EPS visits, hospitalizations.
 - e. Major accidents/injuries including head injuries and sources of chronic pain.
 - f. Hospitalizations
 - g. Surgeries
7. Required labs are order per standardized Nursing Procedures.
8. Medications (note any concerns about interactions with MAT):
 - a. Prescribed
 - b. OTC
 - c. Herbals & dietary supplements
 - d. Labs on admission (see section S for details)
9. Run CURES and document your observation prior to or at start of a controlled medication and every six months thereafter.
10. Current Medical Providers
 - a. PCP
 - b. Psychiatrist
 - c. Ob/Gyn
 - d. Other specialists
11. Allergies and Adverse Reactions
12. Family History
 - a. Cardiac conditions, such as MI, CHF and congenital heart defects.
 - b. Diabetes and cancer
 - c. Substance use disorder, current status
13. Preventive Health

- a. Date of last screening for TB
- b. Risk factors and date of last screening for HIV
- c. Date of last Tdap
- d. Date of last flu shot and COVID vaccine
- e. Date of last PAP/pelvic, mammogram

14. EKG

- a. Review previous (if available)
- b. If admission is delayed for pre-induction EKG, document the reason (personal or family history, personal risk factors, medications, co-occurring conditions or symptoms and refer as necessary.
- c. If serial EKG monitoring is necessary, indicate the reason, who will be responsible (MAT MD or PCP) for ordering and recommended frequency.

15. Review of Systems

- a. General
- b. Organ systems especially cardiac, pulmonary or hepatic impairment.
- c. Mental Health including inquiry about suicidality/homicidality.

16. Physical Exam

- a. Meeting state and federal regulatory requirements.
- b. Including signs of opioid withdrawal and evidence of past or recent injection.
- c. Documenting presence of chaperone if applicable.

17. Assessment & Plan

- a. List each substance for which patient meets criteria for a use disorder and any treatment recommendations.
- b. For patients seeking MAT for opioid use disorder, document presence or absence of opioid use disorder, based on DSM 5 criteria, and the treatment options available given patient's overall history, clinical presentation, co-occurring use disorders, mental health status and regulatory requirements. Document discussion of risks and benefits of medication(s), a specific medication/treatment recommendation and plan, including starting dose of medication and post-dose observation period. Federal Medication consent form to be reviewed with patient by dispensing nurse prior to administration of the first dose.
- c. For patients who are pregnant, document that the risks and benefits of medication assisted treatment with methadone vs buprenorphine (during pregnancy and at delivery) were discussed as well as the requirements for more frequent MD follow-up visits and urine drug testing. Document source of prenatal care, plan to

address if not in care and necessity of coordination of care with prenatal and pediatric care providers.

Document any additional medical assessment/treatment needed prior to or concurrent with substance use treatment. In the event of acute mental health or other medical concerns, document risk assessment and plan to address.

18. Document patient education related to:

- a. Risk vs. benefit of MAT including side effects
- b. Drug-drug and drug-disease interactions (i.e. Hepatic dysfunction)
- c. Plans to minimize the risk of overdose and other events i.e. DUI
- d. Risk of concomitant use of BZDs, Alc. And other CNS depressants with MAT
- e. Drug/blood alcohol level and daily dosing
- e. Induction process
- f. Programmatic requirements

19. Physician signature

B. The Physician's follow up Progress Notes should contain the following:

***All various types of progress notes should include** Date, Location where service was provided, purpose and duration of visit

I. Short face to face progress notes should include:

1. Current MAT dose and step level
2. Chief Complaint
3. Assessment
4. Plan
5. Follow up: labs or diagnostic tests ordered (ekg/trough etc.).

II. Chart review/Verbal Orders documentation requirements:

1. Nature of request
2. Assessment
3. Plan
4. Prescriber's signature

III. Face to face medication **follow up progress notes** should include:

1. Vitals signs, BAL (for in person visit)
2. Patient's report of symptoms on current dose
3. Observation of withdrawal or intoxication
4. Notation of missed doses (if problematic) and discussion with patient to address

5. Impact of dose on opioid use
6. Status of use of other substances if clinically indicated
7. Assessment of medication side effects and plan to address
8. New medical concerns and/or status of conditions identified at prior visits and access to necessary medical care
9. Assessment of adequacy of current dose given symptoms reported by patient.
10. Rationale for changing or maintaining current dose of medication.
11. Patient education as needed
12. Follow up plan

IV. Annual Medical Review, documentation should include:

1. Vitals, BAL, updated weight (if in person)
2. Review and update of medical providers
3. Review and update of medications
4. Review and update of medication allergies
5. Review CURES report
6. Review and update of hospitalization in the past year
7. List of patient's current health concerns and general life concerns
8. Review of Systems including mental health
9. Review of preventive health issues
 - a. TB screening
 - b. Date of last Tdap
 - c. Date of last flu shot
 - d. For women, date of last routine GYN care
 - e. Risk factors for HIV
 - f. Vaccination for Hepatitis A & B, if indication and/or Treatment of Hepatitis C
 - g. Contraception
10. Review of annual labs
11. Review of EKG or referral if indicated
12. Review of patient education as needed
13. Progress in recovery
 - a. Opioids
 1. Date of last use of opioids, frequency of use
 2. Presence of craving
 3. Methadone or buprenorphine dose review
 - i. Adequate?
 - ii. Ill effects?
 - iii. Review methadone blood levels, if applicable
 - iv. Plan to address

- b. Other substances, (including stimulants, sedatives, hallucinogens, marijuana, alcohol, and tobacco.
 - 1. Date of last use, frequency of use
 - 2. Presence of craving
 - 3. Is pharmacotherapy underway or indicated (bupropion, nicotine replacement, Chantix)
 - 4. Patient education related to concomitant use of above substances with MAT
 - 5. Plan to address
- 14. Physical Exam
 - a. Generally, every 3 years, unless indicated sooner.
 - b. May be waived if exam is documented/being done elsewhere (Healthlink or Care Everywhere, Kaiser).
- 15. Overall impression of progress in treatment, status in recovery, stage of change, adequacy/appropriateness of methadone dose and status of mental health and other medical problems.
- 16. Recommendations regarding methadone dose and plan to address substance use, mental health and other medical problems identified and to follow up with recommended preventive health care.
- 17. Coordination of care with other providers as needed.
- 18. Physician Signature

C. Monthly follow-up of Pregnant Woman on Methadone

Document the discussion of the following at each appointment and/or as frequently as clinically indicated:

- I. Pregnancy-related
 - a. Due date & gestational age
 - b. Participation in prenatal care
 - c. Prenatal care provider's concerns
 - d. Current medications and concerns with drug interactions and Methadone (If any DDIs present)
 - e. Drug-drug interactions and clearance of medications during Pregnancy.
 - f. Cramping, spotting, fetal movement
 - g. Response to pregnancy, readiness for motherhood
- II. Substance Use related:
 - a. Opioids
 - i. Last use, frequency of use
 - ii. Craving
 - iii. Current methadone dose
 - 1. Dosing pattern

2. Symptoms of withdrawal between doses
3. Adverse effects
4. Appropriateness of current dose
- b. Other substances used:
 - i. Last use, frequency of use
 - ii. Craving
 - iii. Is pharmacotherapy underway or indicated (bupropion, nicotine gum)
- c. Participation in the Perinatal Substance Abuse Program
 - i. Frequency of counseling
 - ii. Frequency of meetings with Health Educator
 - iii. Pre- and post- COVID-9 Frequency of group attendance

III. Medical Counsel (tailored to individual need and trimester of pregnancy):

- a. Impact of specific substance use on patient, pregnancy, and baby.
- b. Importance of participation in prenatal, postpartum, and pediatric care.
- c. Impact of opioid withdrawal on patient, pregnancy, and baby.
- d. Neonatal abstinence syndrome – symptoms, factors affecting severity, treatment, impact of subtherapeutic methadone dose and use of cigarettes, alcohol, etc.
- e. Post-partum depression – symptoms, treatment
- f. Risk of relapse after delivery
- g. Impact of pregnancy and delivery on methadone metabolism
- h. Breastfeeding – factors to consider

IV. Social concerns (as raised by patient)

- a. Homelessness
- b. Issues with FOB
- c. Issues with family
- d. Domestic violence

I. If for Post-Delivery Review

1. Delivery history

- a. Date and hospital's name
- b. Type of delivery
- c. Complications and duration of hospital stay
- d. post-partum checkup and contraception status

2. The baby

- a. Gender and name (First & Last)

- b. Weight
- c. NAS present, if so the treatment
- d. Other medical problems
- e. Method of feeding

3. Medical follow up if needed

- a. Treatment of Latent TB Infection if relevant
- b. Treatment of HCV if indicated
- c. Procedures/referrals deferred if any

4. Mental Health

- a. Symptoms of Post-Partum depression or other diagnoses
- b. Mental Provider's name and the medications

5. Recovery

- a. Last use- list drugs and dates
- b. Craving/drug dreams
- c. Methadone/Buprenorphine dose evaluation
- d. Statement of fitness to continue MAT

E. Side Effects of Methadone Oral Concentrate (Refer to Section S Side effects for details)

The major hazards of methadone are:

Respiratory depression and, to a lesser degree, systemic hypotension. Respiratory arrest, shock, cardiac arrest, and death have occurred.

The most frequently observed adverse reactions include:

Lightheadedness, dizziness, sedation, nausea, vomiting, and sweating. These effects seem to be more prominent in ambulatory patients and in those who are not suffering severe pain. In such individuals, lower doses are advisable.

Other adverse reactions include the following: (listed alphabetically under each subsection)

Body as a Whole – asthenia (weakness), edema, headache

Cardiovascular (see **WARNINGS: Cardiac Conduction Effects**) – arrhythmias, bigeminal rhythms, bradycardia, cardiomyopathy, ECG abnormalities, extrasystoles, flushing, heart failure, hypotension, palpitations, phlebitis, QT interval prolongation, syncope, T-wave inversion, tachycardia, torsade de pointes, ventricular fibrillation, ventricular tachycardia NDA 17-116/S-021 Page 31

Digestive – abdominal pain, anorexia, biliary tract spasm, constipation, dry mouth, glossitis
Hematologic and Lymphatic – reversible thrombocytopenia has been described in opioid addicts with chronic hepatitis

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Metabolic and Nutritional – hypokalemia, hypomagnesemia, weight gain

Nervous – agitation, confusion, disorientation, dysphoria, euphoria, insomnia, seizures

Respiratory – pulmonary edema, respiratory depression (see **WARNINGS: Respiratory Depression**)

Skin and Appendages – pruritis, urticaria, other skin rashes, and rarely, hemorrhagic urticaria

Special Senses – hallucinations, visual disturbances

Urogenital – amenorrhea, antidiuretic effect, reduced libido and/or potency, urinary retention or hesitancy

Maintenance on a Stabilized Dose – During prolonged administration of methadone, as in a methadone maintenance treatment program, there is usually a gradual, yet progressive, disappearance of side effects over a period of several weeks. However, constipation and sweating often persist.

(From the Mallinckrodt label, revised 12/2016)

[METHADOSE Label \(fda.gov\)](#)